REMARKS

Favorable reconsideration of this application is requested in view of the following remarks.

Claim 1 has been amended editorially. Claim 9 has been amended editorially as suggested.

The amendments to the specification were objected to under 35 U.S.C. 132(a). The revisions to the specification have been clarified to track original claims 2, 8, and 10. Accordingly, no new matter has been included, and this objection should be withdrawn. Applicants respectfully note that the upper limit of "about 90 %" of methacrylic acid copolymer in the composition in the paragraph beginning on page 4, line 7 and that of "about 40 %" of opacifier in the composition in the paragraph beginning on page 4, line 21 are disclosed in the respective paragraphs of the original specification.

Claims 9 and 10 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Current claim 9 recites the limitations as the enteric film coating dry powder "further comprising at least one pigment selected from..." as suggested. Accordingly, this rejection should be withdrawn.

Claim 1-8, 11-15, and 18 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Mehra et al. (U.S. Patent No. 5,733,575). Applicants respectfully traverse this rejection.

Deshpande is directed to providing a stable pharmaceutical composition including an acid unstable active ingredient by having a two-layer coating including the inner layer formed at neutral or near neutral pH and the outer layer formed at acidic pH (see abstract, paras. [0033] and [0036] on page 2, and paras. [0073]-[0074] on page 5). The inner layer of Deshpande protects the acid unstable active ingredient from the outer acidic pH layer

during storage of the pharmaceutical product (see para. [0040] on page 3). The acidic pH outer layer serves as an enteric coating and protects the acid unstable active ingredient from stomach acids (see *id.*). If the outer layer of Deshpande alone were considered as the enteric film coating composition, the reference fails to disclose the concentration of methacrylate copolymer of Type C of about 20-90 wt% in the outer layer, and none of the outer layer compositions in examples of the reference includes the particular composition including the plasticizer, a film coating detackifier, and an opacifier in addition to about 20-90 wt% methacrylate copolymer of Type C and excluding the alkalinizing agent as claim 1 recites (see examples 1-4 on pages 3-4 of the reference). Desphande does not teach or suggest that the inner layer alone is an enteric coating (see para. [0040]).

In addition, even if the combination of the outer and inner layers of Deshpande were considered as the enteric coating, which Applicants do not concede, Deshpande includes 2M ammonia solution in suspension of the inner layer composition, i.e., the alkalinizing agent, which claim 1 excludes from the composition, in order to adjust pH to neutral or nearly neutral (see *id.*). Although the alkalinizing agent such as 2M ammonia solution is added to a suspension in a liquid form, the alkalinizing agent is an essential element for the inner layer composition of Deshpande to obtain the neutral or near neutral pH and protect the acid unstable active ingredient from the outer acidic pH layer as discussed above (see para. [0038] on page 2 and para. [0040] on page 3). The composition does not include the essential element, and thus there is no reasonable basis to assume that the composition excluding the essential element, i.e., alkalinizing agent, would exhibit the same properties as those of the composition including the essential element. By having one composition for enteric film coating excluding the alkalinizing agent as claim 1 recites, the composition is readily dispersible in water without caking or agglomeration, and the coating film has good tensile strength, has good stability, and is tack free (see "Summary of the invention" on pages 2-3 of the specification). Such properties obtained with one enteric coating composition excluding the alkalinizing agent, which is commonly used to increase stability of the coating (see last para. on page 2 of the specification), are unexpected from Deshpande. Also, it is clearly advantageous for a pharmaceutical formulation to have one coating layer, which requires a fewer steps than the formulation having two coating layers, particularly in commercial production.

Accordingly, claim 1 and claims 2-8, 12-15, and 18, which ultimately depend from claim 1, are distinguished from Deshpande.

Similar to claim 1, claim 11 recites one fully formulated enteric film coating composition for one aqueous enteric suspension, which includes about 20-90 wt% of a methacrylate copolymer of Type C, a plasticizer, a film coating detackifier, and an opacifier, and does not include the alkalinizing agent. Accordingly, claim 11 is distinguished from Deshpande for at least the same reasons as discussed for claim 1 above.

Mehra fails to disclose the particular enteric film coating composition including about 20-90 wt% of methacrylate copolymer of Type C, the plasticizer, a film coating detackifier, and an opacifier as claim 1 recites. Mehra discloses an enteric film coating composition including an anti-coagulating/alkalinizing agent (see coln. 2, lines 21-29), and the Mehra reference teaches away from the enteric film coating dry powder composition of claim 1 that excludes the alkalinizing agent.

For at least the same reasons as discussed for claim 1 above, Mehra teaches away from the enteric film coating composition of claim 11, which also recites the particular enteric film coating composition including about 20-90 wt% of methacrylate copolymer of Type C, the plasticizer, a film coating detackifier, and an opacifier and excluding the alkalinizing agent. Accordingly, Mehra does not remedy the deficiencies of Deshpande, and this rejection should be withdrawn.

Claim 9, 10, 16, and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Mehra et al. (U.S. Patent No. 5,733,575) and Kokubo et al. (U.S. Patent No. 4,948,622). Applicants respectfully traverse this rejection.

Claims 9, 10, and 16, which ultimately depend from claim 1, and claim 17, which depends from claim 11, are distinguished from Deshpande in view of Mehra for at least the same reasons as discussed for claims 1 and 11 above.

Kokubo is directed to a two-layer coating of a solid medicament form that masks bitterness of the ingredient (see abstract). The two-layer coating of Kokubo does not include methacrylate copolymer of Type C (see coln. 2, lines 44-62). The composition of

Kokubo, which provides a coating that masks bitterness of the ingredient, is completely different from those for the enteric coatings of Deshpande and Mehra, which prevent release of the active ingredient in stomach acids (see abstract, respectively). Thus, there is no reasonable basis to combine Kokubo with Deshpande and Mehra, and Kokubo does not remedy the deficiencies of Deshpande and Mehra. Accordingly, this rejection should be withdrawn.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.

Respectfully submitted,

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